

## INTRODUCTION

Claims 1, 2, 4, 8, 10, 12, 15 and 19 remain in the case and favorable consideration in view of the above claim amendments and the following remarks and references submitted in support thereof is requested.

The patent application claims define a method of treating acne caused by the bacterium *Propionibacterium acnes*, by topically applying to the skin of a patient needing treatment for acne, a composition comprising grape seed extract as the active ingredient in an amount sufficient to inhibit the growth of the bacterium *Propionibacterium acnes*. The patent application claims also define a topical composition for the treatment of acne caused by the bacterium *Propionibacterium acnes*. The whole point of the invention is to inhibit the bacterium *Propionibacterium acnes* responsible for causing acne and thereby treat the acne caused by that bacterium.

The present invention, on the other hand, has nothing to do with the treatment of rosacea or, as it is sometimes called, acne rosacea. Acne caused by the bacterium *Propionibacterium acnes* and rosacea (or acne rosacea) are not the same. This is explained in more detail below.

## THE REJECTION OF THE CLAIMS

### A. Procedural Rejections

Claims 1, 8 and 15 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

Applicant believes that claims 2, 4 and 10 were intended to be rejected under 35 U.S.C. § 112, second paragraph, instead of claims 1, 8 and 15, because reasons for such rejection of claims 2, 4 and 10 were provided on page 2 of the Office Action.

Applicant nevertheless believes that claims 1, 8 and 15 meet the section 112, second paragraph, requirement. In addition, these claims have been amended to further clarify that the acne is caused by the bacterium *Propionibacterium acnes*.

As for the section 112, second paragraph rejection of claim 2, Applicant has cancelled the claim in order to expedite allowance.

Moreover, the rejection of claims 4 and 10 because of the terms “fatty acid derived” and “modified” has been resolved by deleting those terms from the claims in order to obtain an expedited allowance.

In view of the foregoing comments and claim amendments, reconsideration of the section 112, second paragraph, rejection is respectfully requested.

#### THE PRIOR ART REJECTIONS

##### A. The Anticipation Rejection

Claims 1, 2, 4, 8, 10 and 15 were rejected under 35 U.S.C. § 102(b) as being unpatentable over Cals-Grieson (WO 01/82887 A1 - translation in US 2003/0165589 A1). The Office Action states that this reference discloses a “topical composition comprising grape seed extract with a method of treating acne.” The Office Action cites to paragraphs 22 and 30 of that reference as disclosing grape extract for treating acne. This rejection is respectfully traversed.

As the Examiner is aware, for there to be a section 102 rejection, all the elements of the claimed invention must be the same (exactly the same) as in the prior art reference. Here, that is not the case.

The prior art reference teaches that the prior art composition is “intended to treat **acne rosacea**” (see US 2003/0165589 A1 [33] emphasis added), which is not the same thing as acne caused by the bacterium *Propionibacterium acnes* as claimed in the present invention.

The whole idea of the prior art reference is to inhibit NO-synthase. The reference states [at paragraph 0007] that NO plays a predominant role in the skin, and is involved in cellular differentiation and proliferation [see paragraph 0008]. The prior art reference, however, teaches nothing about using grape seed extract to treat acne caused by the bacterium *Propionibacterium acnes*. In fact, the prior art reference contemplates using other actives like “antibacterial agents, such as clindamycin phosphate or erythromycin or antibiotics of the tetracyclin family” [see paragraph 0081]. Such antibacterial agents are not necessary with the present invention.

More importantly, as indicated in the enclosed three publications:

- (1) Bikowski, Joseph B., Subantimicrobial Dose Doxycycline for Acne and Rosacea;
- (2) Webster, Guy F., Acne Vulgaris and Rosacea: Evaluation and Management; and
- (3) McHugh, RC, et al, A Topical Azithromycin Preparation for the Treatment of Acne Vulgaris and Rosacea -- acne and acne rosacea are not the same and in fact are quite different.

Bikowski states that acne (or as it is sometimes called acne vulgaris) and acne rosacea (or rosacea) are “pathophysiologically distinct” and that one of the factors contributing to the pathogenesis of acne is *Propionibacterium acnes* -“driven inflammation” and “inflammation (and subsequently, inflammatory acne) is a direct or indirect result of the proliferation of” the bacterium *Propionibacterium acnes* (at page 234).

Bikowski reports that rosacea, on the other hand, is a “cutaneous vascular disorder” and “the etiology of rosacea remains unclear” (at page 235). Bikowski contrasts acne and rosacea by saying that “[t]reatment of acne focuses on the resolution of inflammation [but with] rosacea, therapy is typically anti-inflammatory in nature.”

Webster confirms what Bikowski teaches by stating that acne vulgaris is commonly termed acne and that its pathogenesis is multifactorial. “The target of inflammation is *Propionibacterium acnes*, an aerotolerant anaerobic member of the normal flora in sebaceous regions of the skin.” (at p. page 15). Webster also reports that the “cause of rosacea is uncertain.

McHugh reports that the disease mechanism of acne vulgaris “is attributed to hyperkeratotic follicular plugging and sebum accumulation, bacterial breakdown of sebum, and release of inflammatory mediators such as free fatty acids.” (at page 296). It is the bacterium *Propionibacterium acnes* that causes the “breakdown of sebum, and release of inflammatory mediators.”

McHugh also indicates that “[r]osacea can be distinguished from acne vulgaris through the absence of comedones” (at page 301). To further show the difference

between acne and rosacea, McHugh reports that the antibiotic azithromycin gave “statistically significant improvement with inflammatory lesions” in the treatment of acne, but “no significant reductions in the number of rosacea lesions” (see page 301).

For all of the above reasons, Applicant respectfully requests reconsideration of the section 102(b) rejection and that the rejection be withdrawn.

B. The Obviousness Rejection

Claims 8, 12, 15 and 19 were rejected under 35 U.S.C. § 103(a) as unpatentable over the same Cals-Grierson reference (WO 01/82887 A1 - translation in US 2003/0165589 A1). The Office Action states that this reference is relied upon for the reasons discussed in the anticipation rejection.

This rejection is respectfully traversed.

As pointed out above, acne (acne vulgaris) and rosacea (or acne rosacea) are not the same thing. It is known that *Propionibacterium acnes* contributes to acne. It is not known what causes rosacea. It therefore would not be reasonable to assume that if something works for rosacea it would work for acne. In fact, the evidence of record is that an active ingredient may work for one but not the other, see the azithromycin example discussed above wherein McHugh reports that the antibiotic azithromycin gave “statistically significant improvement with inflammatory lesions” in the treatment of acne, but “no significant reductions in the number of rosacea lesions” (see page 301).

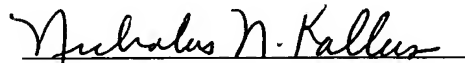
For all these reasons, Applicant respectfully requests reconsideration of the section 103 rejection and that the rejection be withdrawn.

### CONCLUSION

Accordingly, based on the claim amendments and the evidence and argument presented above, it is respectfully submitted that the section 112, second paragraph, section 102(b) and section 103 rejections should be withdrawn and the case allowed to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Nicholas N. Kallas

Attorneys for Applicants

Registration No. 31,530

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
Facsimile: (212) 218-2200